JAN 26 2006

K053518

TAB 4

PREMARKET NOTIFICATION [510(K)] SUMMARY

Trade Name:	InterV brand V-Mark® Breast Biopsy Site Marker with Titanium Anchor
Common Name:	Biopsy Site Marker
Classification Name:	Implantable staple (per 21 CFR section 878.4750)
510(k) Owner's and Manufacturer's Name:	Medical Device Technologies 3600 SW 47th Avenue Gainesville, FL 32608 Tel: 352-338-0440 Fax: 352-338-0662
Corresponding Official:	Kristine Liberacki Manager Regulatory Affairs and Quality Assurance 3600 SW 47th Avenue Gainesville, FL 32608 (800) 338-0440 ext 350 Fax: 352-338-0662
Predicate Device(s):	Medical Device Technologies, Inc. InterV brand V-Mark Breast Biopsy Site Marker, K051421.
Device Description:	The V-Mark Breast Biopsy Site Marker is made of a resorbable copolymer, a polyester derivative of lactic and glycolic acids. Polylactic/polyglycolic acid copolymers degrade and resorb *in vivo* by hydrolysis into lactic and glycolic acids, which are then metabolized by the body. The site markers are deployed through an applicator that fits in commercially available biopsy probes. The V-Mark Breast Biopsy Site Marker marks the site of biopsy tissue sample, and is visible for up to 6 weeks by x-ray, ultrasound and MRI. The body then metabolizes the marker over time. The V-Mark contains a titanium component for permanent radiographic visibility.
Intended Use:	The intended use is identical to the predicate device. The InterV brand V-Mark Breast Biopsy Site Marker with Titanium Anchor is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under MRI

and ultrasound for at least 6 weeks, and be permanently visible by fluoroscopy

Technological Characteristics:

The V-Mark Breast Biopsy Site Marker has been modified to remove the contrast agent that was incorporated into the polymer to provide radiopacity. The titanium component of the device provides for permanent radiographic visibility, eliminating the need for contrast agent in the resorbable polymer. V-Mark Breast Biopsy Site Markers are made of 75/25% poly(D,L-lactide-co-glycolide) copolymer. No other changes have been made to the formulation other than the elimination of the contrast agent.

The site markers are deployed into the biopsy needle tract using a hand held applicator with a two finger-push control rod that delivers a single marker. The site markers are deployed through an applicator that fits commercially available biopsy probes or coaxial needles including the J&J Ethicon Mammotome biopsy probe, the Pro-Mag Coaxial Introducer with Blunt Obturator, the Bio-Pince Co-axial Introducer with Blunt Obturator, the Medical Device Technologies V-Core Co-axial Introducer, and the Suros Vacuum Assisted Biopsy System. For physicians who desire to perform biopsy under ultrasound guidance, a delivery system cannula with an echogenic tip is also available for multiple coaxial applications.

Non-Clinical Performance Data:

Removal of contrast agent from the polymer did not affect device performance. Wire retention in the polymer without contrast was equivalent to retention in polymer with contrast. Finished product testing of the device without contrast, including deployment through the delivery system, met the original design specifications. All testing was performed post sterilization. The results support a determination that the modified device is substantially equivalent to the original product.

Conclusions:

The V-Mark Breast Biopsy Site Marker, modified to eliminate the contrast agent from the original formulation, is substantially equivalent to the original product and meets the same finished product specifications for performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

Ms. Kristine Liberacki
Manager, Regulatory Affairs and Quality Assurance
Medical Device Technologies, Inc.
3600 Southwest 47th Avenue
Gainesville, Florida 32608

Re: K053518
Trade/Device Name: InterV® brand V-Mark™ Breast Biopsy Site Marker with Titanium Anchor
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: NEU
Dated: January 17, 2006
Received: January 20, 2006

Dear Ms. Liberacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchner

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TAB 3

INDICATIONS FOR USE

510(k) Number: _____

Device Name: InterV® brand V-Mark™ Breast Biopsy Site Marker with Titanium Anchor

Indications for Use:

The InterV brand V-Mark Breast Biopsy Site Marker with Titanium Anchor is intended to mark tissue during a percutaneous breast biopsy procedure, be visible under MRI and ultrasound for at least 6 weeks, and be permanently visible by fluoroscopy.

☒ **Prescription Use** (per 21 CFR 801 Subpart D) or ☐ **Over-The-Counter Use** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053518